

K090919

**Kensey Nash****510(k) Summary**

OCT - 2 2009

**Submitted by:** Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, PA 19341

**Contact Person:** Alyssa J. Schwartz, MS, RAC  
Regulatory Affairs Specialist  
Ph: (484) 713-2173 Fax: (484) 713-2903

**Date Prepared:** March 30, 2009

**510(K) #:**

**Device:**

**Trade Name:** Kensey Nash Fibrillar Collagen Dental Membrane

**Common/Usual Name:** Collagen Dental Membrane

**Proposed Classification:** Barrier, Animal Source, Intraoral  
21 CFR 872.3930, NPL, Class II

**Device Description:**

The Kensey Nash (KN) Fibrillar Collagen Dental Membrane is a translucent, resorbable, non-friable, rectangular collagen membrane sheet derived from bovine tissue. The KN Fibrillar Collagen Dental Membrane is intended for single-use and is sterilized by Ethylene Oxide.

**Intended Use:**

The Kensey Nash Fibrillar Collagen Dental Membrane is indicated for:

- Simultaneous use of Guided Bone Regeneration (GBR)-membrane and implants.
- Augmentation around implants placed in immediate extraction sites.
- Augmentation around implants placed in delayed extraction sockets.
- Localized ridge augmentation for later implantation.
- Alveolar ridge reconstruction for prosthetic treatment.
- Filling of bone defects after root resection, cystectomy, removal of retained teeth.
- Guided bone regeneration in dehiscence defects.
- Guided tissue regeneration procedures in periodontal defects

**Predicate Devices:**

<u>Manufacturer</u>	<u>Device</u>	<u>510(k)#</u>
Geistlich Pharma AG	Bio-Gide	K050466
Collagen Matrix, Inc.	Collagen Dental Membrane – Conformable II	K062881

**Substantial Equivalence:**

Performance Testing has confirmed that the Kensey Nash Fibrillar Collagen Dental Membrane is substantially equivalent to the predicate devices with regard to materials, intended use, and technological characteristics, pursuant to section 510(k).

1-800-524-1984

KENSEY NASH CORPORATION, 735 PENNSYLVANIA DRIVE, EXTON, PA 19341



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

Ms. Alyssa J. Schwartz  
Regulatory Affairs Specialist  
Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, Pennsylvania 19341

OCT - 2 2009

Re: K090919

Trade/Device Name: Kensey Nash Fibrillar Collagen Dental Membrane  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: NPL  
Dated: September 25, 2009  
Received: September 28, 2009

Dear Ms. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., M.A.

Acting Division Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications For Use Statement

**510(k) Number:**

**Device Name:** Kensey Nash Fibrillar Collagen Dental Membrane

**Indications For Use:**

The Kensey Nash Fibrillar Collagen Dental Membrane is indicated for:

- Simultaneous use of GBR-membrane and implants.
- Augmentation around implants placed in immediate extraction sites.
- Augmentation around implants placed in delayed extraction sockets.
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- Alveolar ridge reconstruction for prosthetic treatment.
- Filling of bone defects after root resection, cystectomy, removal of retained teeth.
- Guided bone regeneration in dehiscence defects.
- Guided tissue regeneration procedures in periodontal defects

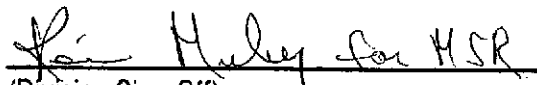
Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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